

What is claimed is:

1. An *in vitro* method of diagnosing the presence of a pre-malignant lesion, a malignancy, or other pathologic condition, in a subject, which is characterized by the presence of activated matriptase comprising the steps of:
 - (A) obtaining a biological sample from a subject that is to be tested for a pre-malignant lesion, a malignancy, or other pathologic condition;
 - (B) exposing the biological sample to a detectable agent which recognizes and binds to activated matriptase; and
 - (C) determining whether said detectable agent is bound to the biological sample.
2. The method of Claim 1, wherein the detectable agent is an antibody.
3. The method of Claim 2, wherein the antibody specifically binds to activated matriptase.
4. The method of Claim 2, wherein the antibody is selected from M69 and M123.
5. The method of Claim 2, wherein the antibody is radiolabeled.
6. The method of Claim 5, wherein the labeled antibody is labeled with a radioisotope or a fluorescent label.
7. The method of Claim 6, wherein the radioisotope is selected from the group consisting of: ^{62}Cu , ^{99}Te , ^{131}I , ^{123}I , ^{111}In , ^{90}Y , ^{188}Re , and ^{186}Re .
8. The method of Claim 2, wherein the method further comprises exposing the biological sample to one or more antibodies which do not specifically bind to active matriptase.
9. The method of Claim 8, wherein at least one of the antibodies which do not specifically bind to active matriptase binds to the inactive form of matriptase.
10. The method of Claim 8, further comprising determining the ratio between the antibody specifically bound to active matriptase and the total of bound antibodies.
11. The method of Claim 10, wherein the antibody specifically binding active matriptase is selected from M69 and M123.

12. The method of Claim 8, wherein the antibody which specifically binds to active matriptase is specific for the conformational changes associated with the proteolytic activation of matriptase.
13. The method of Claim 11, wherein at least one antibody which does not specifically bind to active matriptase is M32.
14. The method of Claim 1, wherein the method further comprises detecting the presence and/or measuring the concentration in the sample of matriptase cognate inhibitor HAI-1 (M58).
15. The method of Claim 1, wherein the biological sample is obtained by biopsy, nipple aspirate, or removal of body fluid that has come into contact with a malignant cell, cells of a pre-malignant lesion, or cells associated with a pathologic condition.
16. A method of treating malignancies, pre-malignant conditions, and pathologic conditions in a subject which are characterized by the activated form of matriptase comprising administering a therapeutically effective amount of an agent capable of blocking the activity of active matriptase.
17. The method of Claim 16, wherein the malignancy and pre-malignant condition is a condition of the breast.
18. The method of Claim 16, wherein the condition involves tissue remodeling; inflammatory responses, smooth muscle cell proliferation; cancer invasion or metastasis.
19. The method of Claim 16, wherein the pre-malignant lesion is selected from the group consisting of: atypical ductal hyperplasia of the breast, actinic keratosis (AK), leukoplakia, Barrett's epithelium (columnar metaplasia) of the esophagus, ulcerative colitis, adenomatous colorectal polyps, erythroplasia of Queyrat, Bowen's disease, bowenoid papulosis, vulvar intraepithelial neoplasia (VIN), and dysplastic changes to the cervix.
20. The method of Claim 16, wherein the matriptase inhibiting agent is an antibody.
21. The method of Claim 20, wherein the antibody is selected from M69 and M123.

22. The method of Claim 16, wherein the malignancy, pre-malignant condition, or other pathologic condition, is in epithelial tissue or in a matriptase expressing tissue.
23. The method of Claim 16, wherein the agent is capable of blocking the activation of matriptase by blocking the activity of an agent capable of inducing the activation of matriptase.
24. The method of Claim 23, wherein the agent capable of inducing the activation of matriptase is compound comprising a lipid moiety.
25. The method of Claim 23, wherein the agent capable of inducing activation of matriptase comprises a lipoprotein.
26. The method of Claim 23, wherein the agent capable of inducing activation of matriptase comprises lysophosphatidic acid (LPA) or shingosine 1-phosphate (S1P).
27. A method of treating pathologic conditions in a subject which are characterized by the lack of the activated form of matriptase comprising administering a therapeutically effective amount of an agent capable of inducing activation of matriptase.
28. The method of Claim 27, wherein the treatment involves wound healing.
29. The method of Claim 27, wherein the agent comprises serum or an extract thereof.
30. The method of Claim 29, wherein the serum comprises bovine; human; horse; goat; mouse; rat; rabbit; duck; or chicken serum; or a mixture thereof.
31. The method of Claim 27, wherein the agent capable of inducing the activation of matriptase is compound comprising a lipid moiety.
32. The method of Claim 27, wherein the agent capable of inducing activation of matriptase comprises a lipoprotein.
33. The method of Claim 27, wherein the agent capable of inducing activation of matriptase comprises lysophosphatidic acid (LPA) or shingosine 1-phosphate (S1P).